

A randomised controlled trial of trans-anal versus trans-vaginal repair for symptomatic anterior rectocele

Submission date 29/09/2006	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 03/09/2013	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0050166862

Study information

Scientific Title

Study objectives

A rectocele is a common problem caused by weakness in the tissues of the pelvis, which leads to problems with defecation. A number of surgical approaches to repair of a rectocele are available. Currently in our institution a patient will have rectocele repair either through the anus or through the vagina. No consensus of opinion exists as to which is the superior approach. The aim of this study is to randomise the patients to one or the other operation to establish which approach is superior.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Rectocele

Interventions

Patients will be selected from the clinics for suitability for surgical repair of their rectocele following appropriate investigations. All patients will be assessed in a structure manner. A specific questionnaire will be filled in by the patient preoperatively. This questionnaire includes SF-36v2 global quality of life assessment tool, the Cleveland continence scoring toll and specific questions on defecation habits, and dyspareunia.

The presence of a symptomatic rectocele in the absence of other pathology renders the patient suitable for inclusion into the trial and after providing adequate information and fully informed

consent they will be randomised to transanal or transvaginal repair. This would happen preoperatively to allow the patient to be counselled and consented about the exact procedure they will undergo.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Functional outcome and quality of life changes by the surgery.

Secondary outcome measures

Not provided at time of registration

Overall study start date

02/06/2005

Completion date

01/02/2006

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

Research participants will be recruited from the outpatient clinic once they have been identified by preoperative investigation to be suitable for surgical repair of their rectocele. Inclusion criteria:

1. The presence of excessive straining, incomplete evacuation
2. The requirement for perineal/vaginal digital pressure during defecation
3. Vaginal bulging and constipation, due to a rectocele as proven on defaecography, in the presence of a normal large bowel.

These are standard indications for rectocele repair.

62 patients will be recruited in to the study from the department of Colorectal Surgery and Gynaecology, 31 patients will be in each arm.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Key exclusion criteria

Patients with a slow transit colon or sphincter defects as these patients have been shown not to benefit from rectocoele repair.

Date of first enrolment

02/06/2005

Date of final enrolment

01/02/2006

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Bradford Royal Infirmary

Bradford

United Kingdom

BD9 6RJ

Sponsor information**Organisation**

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

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SW1A 2NL

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Bradford Teaching Hospitals NHS Foundation Trust (UK) Own Account

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration